



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM22/0303

DISTROLENK, FABER, GERB & SOFFEN
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NEW YORK NY 10036-8403

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/060,765	04/15/98	034	SCHNIZER, H	1653 03/03/00
First Named Applicant	MEHTA,	35 USC 154(b) term ext. =		0 Days.

TITLE OF INVENTION DIRECT EXPRESSION OF PEPTIDES INTO CULTURE MEDIA

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEES DUE	DATE DUE
1 P/546-192	435-069.100	J09	UTILITY	YES	\$605.00	06/05/00

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.
PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS
APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.

Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

FILE COPY**Notice of Allowability**

Application No. 09/060,765	Applic. No. (S) Mehta et al.
Examiner Holly Schnizer	Group Art Unit 1653



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

- This communication is responsive to telephone interview February 28, 2000 (see action attached to this notice).
- The allowed claim(s) is/are 1, 5-15, 20, 22-27, 32-38, 40-43, 67, 70, and 73
- The drawings filed on Jul 6, 1998 are acceptable.
- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) _____
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- Applicant MUST submit NEW FORMAL DRAWINGS
- because the originally filed drawings were declared by applicant to be informal.
- including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. _____.
- including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.
- including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

- Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152
- Interview Summary, PTO-413
- Examiner's Amendment/Comment
- Examiner's Comment Regarding Requirement for Deposit of Biological Material
- Examiner's Statement of Reasons for Allowance

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DETAILED ACTION

Status of the Claims

The Examiner's Amendment below which amends Claims 15, 43, and 67 places the claims in condition for allowance.

Examiner's Amendment

An **examiner's amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Charles C. Achkar on February 28, 2000.

Please amend claims 15, 43, and 67 as follows:

B1 12

15. (twice amended) An expression vector comprising:

(a) a coding region with nucleic acids coding for a peptide product coupled in reading frame 3' of nucleic acids coding for a signal peptide; and

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B1 Conclusion (b) a control region linked operably with the coding region, said control region comprising a plurality of promoters and at least one ribosome binding site, wherein at least one of said promoters is tac,

wherein the C-terminal amino acid of said peptide product is glycine and said peptide product is [selected from the group consisting of] parathyroid hormone [, the first 34 amino acids of parathyroid hormone, and a 35 amino acid peptide having a C-terminal glycine in position 35 and the first 34 amino acids of parathyroid hormone in positions 1-34].

B2 30 45. (twice amended) An expression vector comprising:

(a) a coding region with nucleic acids coding for a peptide product coupled in reading frame 3' of nucleic acids coding for a signal peptide; and
(b) a control region linked operably with the coding region, said control region comprising a plurality of promoters and at least one ribosome binding site, wherein at least one of said promoters is tac,

wherein said peptide product is [selected from the group consisting of] parathyroid hormone [, the first 34 amino acids of parathyroid hormone, and 35 amino acid peptide having a C-terminal glycine in position 35 and the first 34 amino acids of parathyroid hormone in positions 1-34].

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b3 31~~67~~. (twice amended) A method of producing a peptide product which comprises culturing a host cell transformed or transfected with an expression vector in a culture medium and then recovering the peptide product from the medium in which the host cell has been cultured, wherein:

 said peptide product is [selected from the group consisting of] parathyroid hormone [, the first 34 amino acids of parathyroid hormone, and 35 amino acid peptide having a C-terminal glycine in position 35 and the first 34 amino acids of parathyroid hormone in positions 1-34]; and said expression vector comprises:

- (a) a coding region with nucleic acids coding for a peptide product coupled in reading frame 3' of nucleic acids coding for a signal peptide; and
- (b) a control region linked operably with the coding region, said control region comprising a plurality of promoters and at least one ribosome binding site, wherein at least one of said promoters is tac.[.]

Allowable Subject Matter

Claims 1, 5-15, 20, 22-27, 32-38, 40-43, 67, 70, and 73 appear to be free of the art and are allowable for reasons of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached Monday-Thursday from 8:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 306-4119. The fax phone number for Official Papers to this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Holly Schnizer, Ph.D.
February 28, 2000

Karen Cochrane Carlson Ph.D.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER